UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.* RICHARD COHEN, *Plaintiff*, v. LAHEY CLINIC HOSPITAL, INC., *Defendant*.	No. 23–cv–11684–NMG

OPPOSITION TO DEFENDANT LAHEY CLINIC HOSPITAL, INC.'S MOTION TO DISMISS THE RELATOR'S AMENDED COMPLAINT

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INTRODUCTION

Nearly every time Lahey Clinic Hospital, Inc. ("Lahey") treated Relator Richard Cohen for his hemifacial spasms, Lahey fraudulently increased the amount of reimbursement it would receive for the off-label BOTOX treatment it administered.

To accomplish its fraud, Lahey engages in two, simple schemes that capitalize on the fact that Medicare pays for the entire contents of each BOTOX vial, regardless of the amount of drug actually administered. First, Lahey selects and bills Medicare for larger vial sizes than are needed. Second, Lahey overstates the amount of BOTOX actually used or wasted, effectively double billing for the amounts of BOTOX discarded. This case concerns both distinct types of fraud.

Lahey's motion to dismiss rests on three principal arguments. First, Lahey argues that it is not permitted to use 50-unit BOTOX vials to treat Mr. Cohen because "the only drug FDA approved to treat his condition—is packaged and sold in 100-Unit vials." Mem. at 12, 14. This is a specious argument because the BOTOX labeling is silent about treating hemifacial spasms *in any vial size.* The label does not say that BOTOX may be used to treat hemifacial spasms. Rather, it is an **off-label use**, and thus Lahey's argument predicated on compliance with the BOTOX labeling is entirely without merit.

Second, Lahey argues that Mr. Cohen has not sufficiently alleged Lahey's knowledge under the False Claims Act ("FCA"). This argument is also flawed because, with respect to both fraud theories, Mr. Cohen complained to Lahey to no avail; instead of ending the fraudulent practices, Lahey's employees were evasive and allowed the practices to continue. Lahey cannot feign ignorance when the facts show it fully knew.

Third, Lahey claims that Mr. Cohen fails to plead with requisite particularity. This too missed the mark because Plaintiff alleges detailed factual allegations supporting both theories of fraud and identifies numerous instances of specific false claims,

including dates of treatment, vial numbers, amounts billed, amounts administered, and amounts discarded. Mr. Cohen also pinpoints the specific dates when he told Lahey that it was engaged in false billing, the date when Lahey acknowledged it was falsely billing, and the date when a Lahey employee lied to Mr. Cohen to conceal Lahey's fraud. Rule 9(b) is thus satisfied.

Notably absent from Lahey's brief is any suggestion that the claims submitted on behalf of Mr. Cohen correctly stated the amount of BOTOX used, or that Lahey refunded Medicare for the overcharges. Based on the facts alleged in this case, any suggestion that Lahey's claims were simply a "mistake" is idle conjecture. The Court should deny Lahey's motion to dismiss.

BACKGROUND

Mr. Cohen is a Lahey patient who receives treatment under Medicare Part B for his hemifacial spasms, characterized by irregular, involuntary muscle contractions on the left side of his face. AC ¶¶ 73-76. Mr. Cohen's treatment consists of quarterly facial injections of BOTOX. AC ¶ 77. Hemifacial spasm is not an on-label indication for BOTOX. *See* Rodriguez Dec., Ex. 5 at 2, *Indications and Usage*.

On most visits, Mr. Cohen received exactly 16 units of BOTOX, and he never received more than 20 units of BOTOX. AC ¶ 104-105. Yet Lahey typically submitted payment claims for nearly 200 units of BOTOX per visit, far in excess of what Mr. Cohen actually received in treatment. AC ¶¶ 91, 106. Mr. Cohen's treatments could have and should have utilized BOTOX in 50-unit vials, a fact confirmed by a single instance when Lahey did use a 50-unit vial to treat Mr. Cohen. AC ¶¶ 5, 78. However, in all other visits, Defendant submitted false claims for more BOTOX than was medically necessary. AC ¶ 91. Lahey would almost always bill for 180 or more units of BOTOX,

even though Lahey only used a 100 unit vial to treat Mr. Cohen. AC ¶ 91, 98-100. Further, Lahey's use of 100 unit vials to treat Mr. Cohen, who only needed 20 or fewer units of BOTOX, was medically unnecessary because Lahey also purchases and uses 50-unit vials to treat patients. AC ¶ 67-69, 91, 98-100, 106. Lahey knowingly submitted numerous claims—and received payment—for unused BOTOX far in excess of what local coverage determinations and the law allows. AC ¶¶ 3, 44-48.

Mr. Cohen makes these allegations based on direct knowledge and first-hand experience: as a patient at Defendant's BOTOX clinic, Mr. Cohen has on numerous occasions received treatment of **16** units of BOTOX from a single **100**-unit vial of BOTOX, yet later an Explanation of Benefits ("EOB") unambiguously states that the Defendant billed and received payment from Medicare for **184** units of BOTOX. AC ¶¶ 2-3. The following table summarizes the dates of visit, the quantity of BOTOX actually administered, the vial number provided in Dr. Apetauerova's progress notes,[1] and the amount at which Lahey submitted false claims:

Date	Actual Drug Amount Administered	Actual Drug Amount Discarded	Vial Number	Total Units Billed	Number of Units that Should Not Have Been Billed
2020-07-27	14 units	86 units	C6324C 3	186 units	136 units
2020-11-05	14 units	86 units	C6516C 3	100 units	50 units
2021-05-20	16 units	84 units	C6547 C 4	184 units	134 units
2021-08-26	16 units	84 units	C6759 c 4	184 units	134 units

[1] The amount that Dr. Apetauerova recorded as being discarded from each vial is a function of the amount administered and the size of the vial. AC ¶ 94. For example, during Mr. Cohen's May 20, 2021 appointment, Dr. Apetauerova discarded 84 units of BOTOX because she started with a 100-unit vial of BOTOX and administered 16 units of BOTOX from that vial. AC ¶ 94.

Date	Actual Drug Amount Administered	Actual Drug Amount Discarded	Vial Number	Total Units Billed	Number of Units that Should Not Have Been Billed
2021-11-18	16 units	84 units	C6913 c 4	100 units	50 units
2022-02-17	16 units	84 units	C7006 AC 4	184 units	134 units
2022-05-10	16 units	84 units	C7047 C 4	184 units	134 units
2022-08-25	16 units	84 units	C7130 AC 4	182 units	132 units
2022-11-17	20 units	80 units	C7547 C 4	180 units	130 units
TOTALS	144 units	756 units	—	1,484 units	1,034 units

AC ¶ 91.[2]

Lahey's false claims for BOTOX are not limited to Mr. Cohen's treatment, but rather extend to all of Lahey's Government Health Care Program patients who are treated with BOTOX in amounts less than 50 units. *See* AC ¶¶ 95, 115. Consistent with this, when Mr. Cohen asked Lahey representatives why Lahey does not use 50-unit vials of BOTOX, Lahey's Michelle Drover stated in writing that the "clinic only has and uses 100 units and 200 units Botox." AC ¶¶ 95-96. This statement by Lahey's agent constitutes an admission that Lahey fails to use the appropriately sized 50-unit vials (which Lahey does purchase) across its BOTOX-using patients.AC ¶¶ 67-69, 79, 96.

Lahey is aware of the impropriety and of its fraudulent claims for BOTOX but refuses to correct the false claims. AC ¶¶ 111, 113. Indeed, Mr. Cohen has brought these issues to Lahey's attention, but Lahey has failed to correct past false claims or change its

[2] Just across these nine visits by Mr. Cohen, Lahey submitted claims and received payment for 1,484 units of BOTOX, even though it only administered 144 units and discarded 756 units. AC ¶ 92. Lahey's false or fraudulent claims for reimbursement inflated the amount of claims by 1,034 units—a more than seven-fold increase over the amount of drug actually administered to Mr. Cohen. AC ¶ 93.

practices to prevent future false claims. AC ¶ 112. For example, on January 25, 2022, Mr. Cohen called Lahey's billing office about being billed for units in excess of 100 units of BOTOX each visit. AC ¶ 113. On this call, Mr. Cohen spoke to Robin (spelled phonetically) in Lahey's billing office. AC ¶ 113. Mr. Cohen and Robin reviewed the billing records, and Robin agreed that the billed amount was wrong and that she would speak with someone else in the billing office to correct the apparent error and follow up with Mr. Cohen. AC ¶ 113. Mr. Cohen never heard back, and subsequent visits for BOTOX treatment resulted in similarly incorrect billing. AC ¶ 113. The practice of overbilling for BOTOX continues unabated. AC ¶ 114.

ARGUMENT

The Court should deny Lahey's motion to dismiss because the Amended Complaint sets forth sufficient facts to support Mr. Cohen's claim under the FCA. To state a claim under the FCA, the pleading must establish the following four elements: "(1) claims or statements were made; (2) these claims or statements were false; (3) these falsehoods were material; and (4) these statements were made with scienter of the falsehood." *United States ex rel. Mackillop v. Grand Canyon Educ., Inc.*, 626 F. Supp. 3d 418, 444–45 (D. Mass. 2022) (Young, J.). Lahey's motion does not contest that claims were made or contest the materiality of the statements. Instead, Lahey's motion argues that the claims were not false, that there was an insufficient showing of scienter, and that the allegations lack particularity. The Amended Complaint adequately asserts that Lahey illegally double billed and that Lahey billed for inappropriately sized vials. Both of these fact patterns satisfy the pleading requirements.

I. THE AMENDED COMPLAINT SUFFICIENTLY PLEADS THAT LAHEY SUBMITTED FALSE CLAIMS THAT FRAUDULENTLY OVERBILLED THE QUANTITIES OF BOTOX ACTUALLY WASTED.

The Amended Complaint sets forth a claim based on Lahey's double-billing of waste. Because Medicare reimburses for wastage, Lahey is able to submit a payment claim for the entire amount of a vial, even if Lahey only administers a portion of the vial to a patient. *See* AC ¶ 44. Yet Lahey regularly submitted payment claims that exceeded the amount of the entire vial. For example, on May 20, 2021, Lahey administered to Mr. Cohen 16 units from a 100-unit vial and discarded 84. AC ¶ 83. Lahey then submitted a payment claim falsely stating that it used 184 units of BOTOX. AC ¶ 83. By claiming the wasted 84 units twice, Lahey falsely double billed Medicare.

Lahey does not attempt to mount any defense to the falsity of double-billing, nor could it. *See* Mem. at 13. Instead, for the double-billing theory, Lahey focuses on two other arguments: that the Amended Complaint is insufficient as to Lahey's knowledge of the falsity (Mem. at 13–15) and that the Amended Complaint fails to plead fraud with particularity (Mem. at 17). As explained below, each argument fails.

A. Lahey knew that it was submitting false claims because it admitted that its claims were inaccurate and yet continued to submit those claims.

First, the Amended Complaint makes it clear that Lahey had the requisite scienter. The FCA's scienter requirement defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016). At the pleading stage, "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). In *Wollman*, the court denied a

hospital's motion to dismiss an FCA claim for failure to state a claim because the complaint adequately pleaded scienter. *United States ex rel. Wollman v. Gen. Hosp. Corp.*, 394 F. Supp. 3d 174, 190 (D. Mass. 2019) (Burroughs, J.). The court noted that the complaint identified "specific allegedly false claims," a "broader scheme to defraud Medicare and Medicaid," and "a reaction to internal allegations of non-compliance." *Id.* Discovery was thus appropriate to determine whether the hospital's practices were fraudulent or "part of a good-faith effort to fully comply with a less than perfect regulatory regime." *Id.* at 190–91.

Like the pleading in *Wollman*, the Amended Complaint here establishes the element of scienter. The Amended Complaint pleads that Lahey knew and intended its double-billing. *See* AC ¶¶ 90, 111. Such allegations of knowledge and intent satisfy the scienter requirement. *See* Fed. R. Civ. P. 9(b). Indeed, the Amended Complaint goes much further than simply making general allegations of scienter. First, the complaint lists seven occasions across a two-year period where Lahey consistently (and falsely) double-billed wastage. AC ¶ 91. Second, Lahey never corrected the double-billing for wastage, even after Mr. Cohen pointed out the falsity. AC ¶ 113. To the contrary, Lahey continued to submit false claims for double-billing even after an employee in Lahey's billing office confirmed that the billing was wrong. *Compare* AC ¶ 91, *with* AC ¶ 113. This suggests, if not actual knowledge of falsity, a deliberate indifference to the resulting false claims. Third, the amounts of units Lahey submitted in its billing are facially impossible, as Allergan does not sell—and Lahey does not buy—BOTOX in vials of 180, 182, 184, or 186 units. AC ¶¶ 35, 68–69. Yet these were the total units that Lahey billed for Mr. Cohen's treatments. Lahey's billing of irregular amounts—i.e.,

non-multiples of 50 or 100—compels a conclusion that Lahey was making no "innocent mistake." The Amended Complaint sufficiently pleads scienter.

To argue the contrary, Lahey's memorandum falsely quotes the Amended Complaint out of context to state, as fact, that Lahey only purchases 100- and 200-unit vials. This is untrue. The Amended Complaint alleges that Lahey purchases 50- and 100-unit vials. AC ¶¶ 67-72. Lahey ignores this well-pled allegation and instead relies on a false statement by one of its own employees who wrote that the "clinic only has and uses 100 units and 200 units Botox," AC ¶ 95. Lahey also ignores its own charge data, which shows that Lahey purchases 50-unit vials of BOTOX. AC ¶ 71. Further, Lahey ignores that on September 12, 2019, Lahey used a 50-unit vial of BOTOX to treat Mr. Cohen, which confirms that Lahey does in fact purchase 50-unit vials. AC ¶ 79.

Lahey also attempts to pass off the instances of double-billing as a mistake, but this is improper on a motion to dismiss, where the allegations must be taken as true. Here, there is no dispute that the Amended Complaint alleged Lahey repeatedly double-billed the waste. Moreover, Mr. Cohen pointed out the double-billing to Lahey, and Lahey took no steps to address or correct the false statements. The clear inference from the failure to fix the problem is that Lahey knew what it was doing and intended to keep doing it. Finally, Medicare requires using a billing code for the drug administered and the JW modifier for the amount wasted, such that if you add up the numbers, they *must equal* the size of the vial. *See* AC ¶¶ 57–58. But Lahey's bills do not properly add up, as there are no vial sizes in between 100 and 200 units. This was thus no mere mistake. The Court should therefore deny the motion to dismiss.

B. The Amended Complaint provides sufficient particularities concerning the numerous visits where Lahey double-billed.

The Amended Complaint also states "with particularity the circumstances constituting fraud" for the double-billing claim. Rule 9(b) requires pleading fraud with particularity. Fed. R. Civ. P. 9(b). A pleading satisfies this requirement "by alleging with particularity examples of actual false claims submitted to the government." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 10 (1st Cir. 2016). "By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred." *Id.* In *Wollman*, this Court found that a complaint satisfied this requirement with "specific dates, identification numbers, amounts billed, services, individuals involved, and amounts paid for several claims that relate to improperly conducted overlapping and concurrent surgeries." *Wollman*, 394 F. Supp. 3d at 188. These allegations, "taken as true, show that the example claims at issue were false." *Id.*

The Amended Complaint here does the same. Numerous paragraphs state the specific dates, vial numbers, amounts billed, amounts administered, amounts discarded, the employees and doctors involved, and amounts paid. AC ¶¶ 83–93. The Amended Complaint even includes an excerpt from the explanation of benefits that shows how much Lahey billed and received for the double-billing. AC ¶ 85. The Amended Complaint sets forth Lahey's knowledge about the falsity of these billed amounts—an employee even admitted to Mr. Cohen that she believed the billed amounts to be incorrect. AC ¶ 113. Yet, even on notice, Lahey continued to submit bills for these excess amounts. AC ¶ 114. These examples therefore show that "the filing of a false claim is not merely a possibility, but rather, necessarily occurred." *D'Agostino*, 845 F.3d at 10. This is fraud, pure and simple. Accordingly, Mr. Cohen has alleged the "sine

qua non" of a FCA violation, to wit an "actual false claim." *See Mackillop*, 626 F. Supp. 3d at 445. The Court should reject Lahey's scienter arguments.

C. The Amended Complaint also satisfies the particularity requirement as it relates to other patients.

Because the Amended Complaint provides concrete, specific examples of the fraud, it satisfies the Rule 9(b) particularity requirement; but to the extent that Rule 9(b) requires particularity as to patients other than Mr. Cohen, the Amended Complaint satisfies the requirement as well. Notwithstanding the general requirements of Rule 9(b), the First Circuit has recognized that "Rule 9(b) pleading standards may be relaxed, in an appropriate case, 'when the ***opposing party*** is the ***only*** practical source for discovering the specific facts supporting a pleader's conclusion.'" *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 229 (1st Cir. 2004) (emphasis added) (citing *Boston & Maine Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)). In such cases, "if the facts would be ***peculiarly within the defendants' control***, a court may allow some discovery before requiring that plaintiff plead individual acts of fraud with particularity." *Karvelas*, 360 F.3d at 229. In the context of FCA cases, Rule 9(b) may be satisfied where there are "reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 41 (1st Cir. 2017).

Here, the information concerning the instances where Lahey double-billed discarded BOTOX for other Medicare patients is uniquely in the possession of Lahey. Unlike the relator in *Karvelas*, Mr. Cohen is not an employee of Lahey and does not have access to hospital claim data. *See Karvelas*, 360 F.3d at 223. Yet notwithstanding his outside status, Mr. Cohen is able to supply dates, vial numbers, and the quantities for

specific false claims submitted to Medicare, provides account numbers and amounts charged to specific patients for specific treatments, and identifies individuals involved in the improper billing. *See id.* Mr. Cohen has also alleged that Lahey continued to submit false claims even after learning of the falsity of the claims. Far from lacking specifics, Mr. Cohen pleads a viable false claim theory that passes muster with respect to the indefensible practice of double-billing for waste. Based on the many specific examples of false billing alleged in the Amended Complaint, it is a reasonable inference that Lahey either knowingly or with willful indifference submits other claims in this same fashion, and it would be easy to identify such claims in discovery.

Because the Plaintiff was a patient of Lahey, rather than an insider, this Court should apply the more relaxed standard for Rule 9(b). Mr. Cohen has sufficiently established that false claims for BOTOX waste have been submitted on at least seven occasions. AC ¶ 91. Thus, Mr. Cohen has done more than allege a fraudulent practice, and instead alleges a scheme to defraud Medicare complete with specific instances, based on the instances of fraud for which he has first-hand knowledge. *See United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 264 (D. Mass. 2015), *aff'd sub nom., Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26 (1st Cir. 2016) ("allegations of fraudulent practices are not enough; the complaint must also allege a scheme to cause the submission of false claims to the government.").

While the false and fraudulent claims submitted for Mr. Cohen's treatment at Lahey are enumerated and meet the strictures of Rule 9(b), it is a reasonable inference based on Lahey's failure to correct the double-billing practice that Lahey submitted similar

false claims for other patients that would be unknown to Mr. Cohen without discovery and that are peculiarly within Lahey's control. Dismissal is inappropriate.

II. THE AMENDED COMPLAINT SUFFICIENTLY PLEADS THAT LAHEY SUBMITTED FALSE CLAIMS CERTIFYING THAT IT USED APPROPRIATELY SIZED VIALS.

The Amended Complaint sets forth a second claim based on Lahey's certification that it minimized waste by using appropriately sized vials of BOTOX to treat its patients. Lahey raises three arguments to attack this theory: (1) using 100-unit vials instead of 50-unit vials is not a false claim, (2) Lahey could not have known that using 100-unit vials was false, and (3) the pleading's allegations fail to state fraud with particularity. *See* Mem. at 8–13, 18–20. Each of these arguments is incorrect. As explained below, the Amended Complaint satisfies the falsity, knowledge, and particularity requirements on the vial-size claim.

A. Medicare guidance requires the use of appropriately sized vials; the use of 50-unit vials instead of 100-unit vials to administer 20-unit doses was therefore false.

Medicare guidance requires providers to certify impliedly that they are using appropriately sized vials. The Medicare statute states that "no payment may be made under ... part B for any expenses incurred for items or services ... which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). To help enforce this provision, Medicare drug claims based on units administered require a certification, whether express or implied, that the number of units billed were ***both*** medically necessary ***and*** actually administered. *See United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 278 (D. Mass. 2010) (Young, J.) ("[T]he Complaint

alleges adequately that the Defendants' proximately caused the submission of claims for units of Aranesp that were medically unnecessary or never administered"). *See also Mackillop*, 626 F. Supp. 3d at 447; *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 125 (D. Mass. 2011) (Stearns, J.) ("A claim is legally false under the implied certification theory when a claimant makes no express statement regarding compliance with a statute or regulation, but by submitting a claim, the claimant implies that it has complied with all of the stated conditions for payment."); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829, at *4 (D. Mass. Apr. 27, 2018) (Talwani, J.).

For Part B injectables, the requirements of medical necessity and actual administration and Medicare's promise to pay for drug waste result in a rule that pays for "**the amount of waste**, so long as the amounts administered and discarded are accurate and do not exceed the smallest available vial size." AC ¶ 45 (emphasis added). CMS published MLN Matters Number SE1316 to reflect this rule, stating that providers must use the "smallest dose (vial) available ... that could provide the appropriate dose for the patient." *See* Rodriguez Decl. Ex. 8 at 3. Lahey attempts to distinguish this CMS article as relating solely to two non-BOTOX drugs. *See id.* at 1. Yet that article includes a non–drug-specific section that "clarif[ies] billing guidelines and provide[s] examples of proper billing with a single-dose and discarded drug billing." *Id.* at 3. Furthermore, that article simply reflects what the Medicare statute already requires.

Lahey's position appears to be that there is no prohibition on the size of the vial its physicians select. Lahey argues: "there is no legal or statutory requirement that Lahey must use medication drawn from the smallest vials of BOTOX available, regardless of

whether the BOTOX vial is approved to treat the Relator's condition." Mem. at 8. In other words, Lahey believes that it ***can*** use unnecessarily large vials, and that there is no rule preventing it from using a 200-unit vial and doubling its reimbursement in situations where a smaller vial would suffice. This is both galling and untrue, as Medicare has long stated that "units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient." AC ¶¶ 52–55. Lahey's argument also reveals that it disregards "medical necessity" as a condition for payment. Providers must use the smallest vial needed for the prescribed dose; anything more is medically unnecessary.

Here, because Lahey is charging the government for more units of BOTOX than were needed or ever administered, it is in breach of its certifications and the prohibition against medically unnecessary expenses. Thus, all claims for 100-unit BOTOX vials that Lahey submitted, knowing that only 50 units were necessary for actual administration, are false claims.

B. The labels provide no support for Lahey's argument that it is not allowed to use 50-unit vials of BOTOX to treat hemifacial spasms.

Lahey's argument that it may eschew the smallest necessary vial size hinges on a distinction it attempts to draw between so-called "BOTOX therapeutic" and "BOTOX cosmetic." As support, Lahey cites different labels for BOTOX therapeutic and BOTOX cosmetic and argues that only BOTOX therapeutic is approved to treat Mr. Cohen's condition. Lahey's logic is that it cannot be an FCA violation to use BOTOX in a manner consistent with its labeling. Attractive as Lahey's argument may seem at first blush, it ignores several key facts that completely undermine it.

First, ***hemifacial spasm is an off-label use of BOTOX***. *See* Rodriguez Decl. Ex. 5. Accordingly, all of Lahey's arguments based on the language of the labeling are simply irrelevant. The BOTOX labels contain no information about the treatment of hemifacial spasms. *See, e.g.*, Rodriguez Decl. Exs. 1–5. There are no dosage and administration recommendations for hemifacial spasm in the labeling. *Id.* Thus, the BOTOX labels do not dictate the appropriate vial size for treating hemifacial spasms. With respect to Mr. Cohen, Lahey has *never* followed the label, either in terms of indication or dosage. By using BOTOX to treat hemifacial spasms, Lahey has already deviated from the labeled indications for BOTOX, and as a result it also ignores the instruction that "[i]ndication specific dosage and administration recommendations should be followed." *See* Rodriguez Decl. Ex. 4, at 5; Ex. 5, at 5.

Second, Lahey's suggestion that Medicare prohibits reimbursement for the use of 50-unit BOTOX vials lacks support in the law and the evidence. While Medicare prohibits reimbursement for certain cosmetic procedures, it permits reimbursement for the medically necessary use of onabotulinumtoxinA,[3] which is sold as both "BOTOX cosmetic" and "BOTOX therapeutic." Put simply, nothing prohibits the reimbursement for use of BOTOX marketed as BOTOX "cosmetic," so long as its use is for medical purposes, such as its use to treat Mr. Cohen's hemifacial spasms.

Third, Lahey's argument that it is obliged to use 100-unit BOTOX vials in every case is belied by its knowing use of a 50-unit vial on at least one occasion. AC ¶¶ 78-79. Lahey therefore knew that 50-unit BOTOX vials—marketed as BOTOX cosmetic—could be used to treat Mr. Cohen and that BOTOX was available in a 50-unit vial. AC

[3] *Compare* 42 U.S.C. § 1395y (a)(10) and 42 C.F.R. § 411.15 (h)), *with* Nat'l Gov't Servs., Inc., Local Coverage Determination, Botulinum Toxins (L33646), (May 1, 2021).

¶¶ 78-79, 81, 91. Lahey's feigned concern (as a litigant) for differences between the two BOTOX brands is belied by its failure (as a provider) to draw the same distinction when treating Mr. Cohen's condition. *See* AC ¶ 79. In other words, ***Lahey's*** need to use 50-unit vials for low-dose patients was based on ***its own*** awareness that it could (and, in fact, did) use 50-unit BOTOX vials for therapeutic purposes. Notably, Lahey's sole support for its claim that it only purchases 100- and 200-unit vials is misinformation peddled by its own employee. AC ¶ 95. Taking the Amended Complaint as true, Lahey purchases and uses 50-, and 100-unit vials, AC ¶¶ 67-72, and should have used 50-unit vials here.

Fourth, Lahey's claim that "BOTOX therapeutic" and "BOTOX cosmetic" are not interchangeable is false. For starters, a federal court has already rejected the argument, finding that BOTOX therapeutic and BOTOX cosmetic are identical. *See Allergan, Inc. v. Burwell*, No. CV 13-00264 (RJL), 2016 WL 1298960, at *5 (D.D.C. Mar. 31, 2016). Moreover, the claim concerning interchangeability ignores the well-pled allegation in the Amended Complaint that the two brands are identical. AC ¶ 33. Worse, Lahey's argument is based on a misreading of the BOTOX labels. The labels for both BOTOX brands make it clear that they are not only interchangeable—they are ***identical***. Both BOTOX brands contain OnabotulinumtoxinA, which is "a sterile, vacuum-dried purified botulinum toxin type A, produced from fermentation of Hall strain *Clostridium botulinum* type A." *Compare* Rodriguez Decl. Ex. 5, at 29, *with* Rodriguez Decl. Ex. 6, at 12. Both BOTOX products, regardless of the particular branding, are derived from the same assay method: "The primary release procedure … uses a cell-based potency assay to determine the potency relative to a reference standard. ***The assay is specific to … BOTOX and BOTOX Cosmetic***." *Compare* Rodriguez Decl. Ex. 5, at 29, *with* Rodriguez

Decl. Ex. 6, at 12 (emphasis added). This fact is critical, because Lahey's argument hinges on the labels' discussion of product incomparability across ***different*** assay methods, which does not apply to BOTOX therapeutic and BOTOX cosmetic. *See* Rodriguez Decl. Ex. 5, at 16. For this reason, Lahey's argument concerning interchangeability, based solely on the BOTOX package insert, and not on any scientific evidence or expert testimony, misses the mark.

C. Lahey knew that it could have and should have used 50-unit vials, and yet it chose to use 100-unit vials.

The Amended Complaint also establishes that Lahey knew that it could and should have used the 50-unit vials of BOTOX. The FCA's scienter requirement defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *Escobar*, 579 U.S. at 182. Under the FCA, scienter does not require proof of "specific intent to defraud." *Mackillop*, 626 F. Supp. 3d at 452. At the pleading stage, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). *See also Wollman*, 394 F. Supp. 3d at 190 (denying a hospital's motion to dismiss an FCA claim for failure to state a claim because the complaint identified specific allegations, the general scheme to defraud, and acts by the hospital to conceal the fraud).

Here, Mr. Cohen has alleged knowing violations on the vial-size theory. The Amended Complaint alleges that Lahey purchases 50-unit vials of BOTOX and has used 50-unit vials for therapeutic treatments, such as the treatment of Mr. Cohen's hemifacial spasms. AC ¶ 79. That means that Lahey knew that it could use 50-unit vials to treat hemifacial spasms, even if these vials were branded "cosmetic." Lahey then repeatedly

chose to use 100-unit vials to treat Mr. Cohen, even though none of his treatments required more than twenty units of BOTOX. *See* AC ¶ 91. Lahey then submitted claims for these unnecessarily large vials. *Id.* Furthermore, Lahey later falsely wrote to Mr. Cohen that Lahey did not buy and use 50-unit vials. AC ¶ 95. Such an affirmative falsehood reflects Lahey's consciousness of its own wrongdoing and an effort to conceal the fraud. *See United States v. Passos-Paternina*, 918 F.2d 979, 985 (1st Cir. 1990) (noting that lies permit an inference of consciousness of guilt). By submitting payment claims for 100-unit vials, Lahey therefore knowingly submitted claims for more money than it was entitled to, and thereby violated the FCA. The Amended Complaint states a claim.

D. The Amended Complaint provides sufficient particularities concerning the numerous visits where Lahey used 100-unit vials instead of 50-unit vials.

Lahey's motion questions whether the Amended Complaint satisfies the particularity requirement of Rule 9(b), arguing that the pleading establishes nothing more than mistakes. A pleading satisfies Rule 9(b) "by alleging with particularity examples of actual false claims submitted to the government." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 10 (1st Cir. 2016). "By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred." *Id.*

Here, the Amended Complaint pleads the vial-size fraud with particularity. The pleading states that Lahey purchases and uses both 50- and 100-unit vials, AC ¶¶ 67–72, and that Lahey in fact used a 50-unit vial to treat Mr. Cohen's hemifacial spasms on September 12, 2019. AC ¶ 79. The pleading establishes that on all subsequent visits—enumerated in the Amended Complaint, one-by-one, with dates, vial numbers,

amounts billed, amounts administered, and amounts discarded—, Lahey used 100-unit vials, even though Lahey administered twenty units or less on each visit for Mr. Cohen's treatment. AC ¶ 91. The pleading also establishes that Lahey lied to Mr. Cohen when he asked about the use of 100-unit vials; Lahey falsely told Mr. Cohen that Lahey did not purchase or use 50-unit vials: "clinic only has and uses 100 units and 200 units Botox." AC ¶ 95. This subterfuge permits an inference that Lahey knew such conduct was wrong and attempted to hide it. Together, these facts paint with particularity a picture of Lahey's fraud: that on specific dates, Lahey knowingly and systematically used and filed claims for 100-unit vials when only a 50-unit vial was needed. Accordingly, Mr. Cohen has sufficiently alleged a scheme by which Lahey submits inflated claims to Medicare. *See Hagerty*, 95 F. Supp. 3d at 264.

E. The allegations on the vial-size theory apply across the board to all Lahey patients who did not need 100-unit vials of Botox.

While Mr. Cohen has not detailed each and every instance where Lahey has used excessive vial sizes to pad its revenue, he has sufficiently alleged with particularity that this use of 100-unit vials was standard practice at Lahey. Plaintiff has identified at least nine specific false claims where Lahey fraudulently used 100-unit vials instead of 50-unit vials. AC ¶ 91. And as stated above, when Mr. Cohen inquired as to why the Defendant was not using 50 Unit vials, the response he received was categorical: the "clinic only has and uses 100 units and 200 units Botox." AC ¶ 95. This confirms that Lahey's scheme of using unnecessarily large vials applies beyond Mr. Cohen to all Lahey patients who receive BOTOX treatment. Thus, the inference that such claims were submitted for other Medicare patients rises above mere possibility and gains a high degree of probability that false claims were actually submitted. *See United States ex*

rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009) (a relator can satisfy Rule 9(b) by "providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim."); *United States ex rel. Worsfold v. Pfizer Inc.*, No. CIV.A. 09-11522-NMG, 2013 WL 6195790, at *6 (D. Mass. Nov. 22, 2013) (Gorton, J.) (a relator may satisfy Rule 9(b) by alleging particular details of a scheme to submit false claims paired with "reliable indicia" that lead to a strong inference that false claims were actually submitted). The Amended Complaint thereby satisfies the requirements of Rule 9(b) as to Lahey's other Medicare patients who received larger vials of BOTOX than necessary. The Court should deny the motion to dismiss with respect to claims involving other patients.

CONCLUSION

For the reasons set forth above, Mr. Cohen requests that the Court deny Lahey's motion to dismiss.

Respectfully submitted,
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By his attorneys

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